SLOVENSKI STANDARD
oSIST prEN ISO 9360-1:2026

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Izmenjevalniki toplote in vlage ter filtri dihalnih sistemov za dihalne pline - 1. del: Splošne zahteve (ISO/DIS 9360-1:2026)

Heat and moisture exchangers, and breathing system filters for respired gases - Part 1: Common requirements (ISO/DIS 9360-1:2026)

Anästhesie- und Beatmungsgeräte - Wärme- und Feuchtigkeitsaustauscher und Atemschutzfilter (HMEF) zur Anfeuchtung von Atemgasen beim Menschen - Teil 1: Allgemeine Anforderungen (ISO/DIS 9360-1:2026)

Titre manque — Partie 1: Titre manque

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11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

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Heat and moisture exchangers, and breathing system filters for respired gases —

Part 1: Common requirements

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Foreword

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ISO 9360-1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airway devices and related equipment*.

ISO 9360 consists of the following parts, under the general title *Breathing system filters for anaesthetic and respiratory use*:

— Part 1: Common requirements

— Part 2: Measurement of moisture loss

— Part 3: Measurement of filtration performance

These parts technically revise and replace ISO 9360-1:2000, ISO 9360-2:2001, ISO 23328-1:2008 and ISO 23328-2:2009.

These parts are a combination of the above standards with new and modified requirements, in particular:

— Part 1 combines requirements from ISO 9360-1:2000 and ISO 23328-2:2009

— Part 2 combines requirements from ISO 9360-1:2000 and ISO 9360-2:2001.

— Part 3 are requirements from ISO 23328-1:2008.

Specific changes include:

— layout now follows the format of ISO 18190:202x; and references clauses from ISO 18190

— Colour coding requirements were added to distinguish between *HME*s and *BSF*s

Introduction

The gases generally available for medical use lack sufficient moisture to be physiologically acceptable to the respiratory tract of patients. *Heat and moisture exchangers (HME*) are used to raise the water content and the temperature of the gas delivered to the respiratory tract of spontaneously and non-spontaneously breathing patients. *HME*s are intended to form part of a ventilator breathing system. *HME*s are primarily placed between the patient interface (e.g. Tracheal or Tracheostomy Tube) and the anaesthesia or ventilator breathing set. *HME*s are also intended for use with tracheostomy tube where the *HME* is not designed to connected to a anaesthesia or ventilator breathing set.

Breathing system filters (BSF) are used to reduce particulates, including microorganisms, in gases delivered to and exhaled from patients. *BSF*s are intended to form part of a ventilator breathing system. *BSFs* may be placed between the patient interface and the anaesthesia or ventilator breathing set or placed between the anaesthesia or ventilator breathing set and the anaesthesia or ventilator machine. *BSF* are exposed to various levels of humidity during clinical use.

Many devices combine the characteristics of both an *HME* and a *BSF* in one combined device, called an *HMEF*. *HME*s and *HMEF*s are only intended for use between the patient interface and the anaesthesia or ventilator breathing set.